

# Protecting and Improving the Health of Iowans

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## **COVID-19 Vaccine Information Brief**

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Changes to the document from the previous version are highlighted in yellow.

## **IMPORTANT/NEW COVID-19 Vaccine Information**

Pediatric Pfizer vaccinations for 5–11-year olds <u>cannot</u> begin until after ACIP recommendations are signed by the CDC Director

- IDPH Resource COVID-19 Vaccine Additional Dose and Booster Guidelines-Infographic
- New CDC Resources
- ACIP Meeting Agenda and Webcast Link
- Moderna Ancillary Kits
- Adjusting Moderna Boost Doses in IRIS
- Pfizer Pediatric Vaccine Information Administration of doses must wait for ACIP recommendation

## New IDPH Resource - COVID-19 Vaccine Additional Dose and Booster Guidelines Infographic

IDPH has developed an algorithm to assist with determining additional COVID-19 vaccine doses and booster doses.

COVID-19 Vaccine Additional Dose and Booster Guidelines - Infographic

#### **New CDC Resources**

New Federal Standing Orders have been posted on the CDC site to include language about all booster doses.

- Moderna Standing Order
- Janssen Standing Order
- <u>Pfizer Standing Order</u>

An updated Quick Reference Guide is also available.

## **ACIP Meeting for Pfizer Pediatric Vaccine**

The ACIP is scheduled to meet November 2-3, 2021 to provide clinical recommendations for Pfizer's pediatric COVID-19 vaccine. A draft agenda has been released.

- ACIP draft agenda
- ACIP webcast link

## **Moderna Ancillary Kits**

Currently, the ancillary kits for Moderna 14 contain a combination of 1mL and 3mL syringes. While the 3mL syringes are adequate for extracting a primary series dose (0.5 mL), they do not support extraction of the booster dose (0.25 mL). The 1 mL syringes allow for better visualization and extraction of the smaller 0.25 mL booster dose.

To assure providers have an adequate supply of 1 mL syringes to support extraction of booster doses (0.25 mL) from a Moderna 14 vial, CDC will begin shipping an additional Moderna ancillary kit with all orders. When possible, please use 3 mL syringes for extraction of primary series doses to ensure an adequate supply of 1 mL syringes to support extraction of booster doses from a Moderna vial. Do not puncture the vial stopper more than 20 times.

## **Adjusting Moderna Boost Doses In IRIS**

It is critical to account for every dose of COVID-19 vaccine. Measures should be taken to prevent and minimize COVID-19 vaccine wastage. However, there may be situations when doses cannot be used and must be accounted for in IRIS inventory. The CDC COVID-19 Vaccination Program Provider Agreement requires providers to report the number of doses wasted, unused, spoiled, or expired to IRIS. Health care providers can use the Adjusting COVID-19 Vaccine Inventory for Wastage instructions to adjust COVID-19 vaccine inventory in IRIS. If a half dose of Moderna is wasted, IRIS users can adjust inventory accordingly by selecting 0.5 in the 'Amount' field.

On the Edit Inventory page, navigate to the Modify Quantity On Hand section:

- 1. Select the action of 'Subtract'.
- 2. In the 'Amount' field, enter the number of doses being adjusted (0.5).
- 3. In the Reason dropdown menu, select the adjustment reason code of 'Open vial but not all doses administered' or 'Vaccine drawn into syringe but not administered'. ONLY these reason codes should be used to document COVID-19 vaccine wastage.
- 4. Select the 'Save' button.

Contact the IRIS Help Desk at 800-374-3958 with questions regarding vaccine inventory.

## **Pfizer Pediatric Vaccine Information**

Pediatric Pfizer vaccinations for 5–11-year olds cannot begin until after ACIP recommendations are signed by the CDC Director

The Pfizer-BioNTech vaccine for 5–11-year-olds will be a new product configuration with new packaging, new preparation, and a new national drug code (NDC). The current product for adults and adolescents should not be used for children. The Pfizer-BioNTech vaccine for 5–11-year-olds will be a two dose series. The ACIP will provide minimal interval recommendations at the November meeting.

#### Vaccine Storage and Handling

- The product will be delivered in a newly updated product shipper at -80°C. The shipper is disposable and does not need to be returned to Pfizer. The shipper CANNOT be used for vaccine storage.
- Once the product arrives at the provider site, it can be stored for up to 10 weeks at 2 to 8°C and 6 months at ultra cold temperatures of -90 to -60°C.
- Pfizer COVID-19 pediatric vaccine cannot be stored in the freezer.

Once open, doses in vials should be used within 6 hours. Clinics should consider vial size (10-doses) and 6-hour timeframe when scheduling children for vaccination, especially early in the program to minimize waste and optimize use of supply.

#### **Shippers**

Pfizer pediatric vaccines will be shipped on dry ice in smaller disposable shippers. Unlike the adult shippers,



these smaller shippers cannot be used for temporary storage. The contents MUST be removed and placed in a refrigerator or ultra-cold freezer as soon as the order is received. (See storage table below). Do not store Pfizer pediatric COVID-19 vaccine in a standard freezer. The shipper is disposable and does not need to be returned to Pfizer.

## **Controlant Temperature**

#### **Monitoring**

Shipping boxes will continue to contain the familiar Controlant temperature monitor. The shipper should be unpacked immediately upon delivery. Check the temperature monitor for any excursion warnings, turn the monitor off, and return it in the package provided.



#### **Pediatric Vaccine Vials and Diluent**

Pediatric vials come packaged in cartons of 10 vials each. Vials come with a distinctive orange cap, orange striping on the label, and orange striping on the carton. Each vial will be filled to 1.3mL before dilution. The pediatric formula will continue to require addition of 1.3mL of diluent (1:1 ratio) and will contain 10 doses per vial. Orders of Pfizer pediatric vaccine include ancillary kits that contain 10mL diluent vials. While these vials



appear to contain sufficient diluent for multiple vials, they must only be used once.

- Diluent vials are a one-time-use item and should be discarded with the remaining content after each use.
- For each vial of vaccine, extract 1.3mL of diluent from a single-use vial to reconstitute 1.3mL of vaccine.
- Do not be tempted to puncture diluent vials more than once.

#### **Storage and Handling**

- The product will be delivered in a newly updated product shipper at -80°C.
- The shipper box should be unpacked immediately upon receipt, as indicated on the carton.
- The contents must be placed in an ultra-cold freezer -90°C to -60oC or a refrigerator at 2°C to 8°C. **DO NOT PLACE THE PRODUCT IN THE REGULAR FREEZER.**

- Once the product arrives at the provider site, it can be stored for up to 10 weeks at 2 to 8°C and 6 months at ultra cold temperatures of -90 to -60°C.
- Once open, doses in vials should be used within 6 hours. Clinics should consider vial size (10-doses) and 6-hour timeframe when scheduling children for vaccination, especially early in the program to minimize waste and optimize use of supply.

The table below indicates the length of time the pediatric vials can be stored at each temperature. Note, the 10 weeks in the refrigerator is **not** in addition to the 6 months in the freezer. All conditions for storage must be completed within the overall time frame for expiration. Once expired, the vaccine should be discarded regardless of storage conditions.

Storage Conditions		
Ultra Cold Freezer (-90°C to -60°C)	6 months	
Freezer (-25°C to -15°C)	N/A	
Refrigerator (2°C to 8°C)	10 weeks	

## **Pfizer COVID-19 Medical Updates**

Pfizer Vaccines US Medical Affairs will be hosting "Medical Updates" for its COVID-19 vaccine (with its partner BioNTech) on Tuesdays, at 5pm ET, and Thursdays, at 12pm ET, for the remainder of 2021.

These sessions will be continuously updated to reflect new information and changes that evolve. Such updates will be identified at the start of each session and further explained during each presentation.

#### **November 2021 Sessions**

Please click on the links below to join the sessions at the designated times.

Date & Time	Password
Attendee link – November 1 – 5 PM ET	g9ZmgHaip32
Attendee link – November 2 – 5 PM ET	sJDZQERp325
Attendee link – November 3 – 12 PM ET	82qdN3PppPp
Attendee link – November 4 – 12 PM ET	Y4ZkXdh2bz7
Attendee link – November 5 – 12 PM ET	rJSpNPts332

#### **Moderna COVID-19 Medical Updates**

Moderna will be hosting webinars for vaccination providers to learn more about the Moderna COVID-19 Vaccine booster dose, which has been authorized for emergency use in the United States. There will be no continuing education offered for this webinar. Please register at the link below for one of our available sessions.

Webinar: Important updates on the mRNA-1273 50 μg Booster Dose

- Thursday, November 4<sup>th</sup> at 3pm ET Register here for Nov 4
- Thursday, November 11<sup>th</sup> at 12pm ET Register here for Nov 11

## CDC's Advisory Committee Recommends Johnson & Johnson Booster Dose for Adults

CDC's independent advisory committee, the Advisory Committee on Immunization Practices (ACIP) voted on October 21, 2021 to recommend a booster dose of Johnson & Johnson COVID-19 vaccine.

#### **Effective immediately, CDC recommends:**

- People aged ≥18 years who received a single dose Janssen primary series (1 dose) should receive a
  COVID-19 booster dose at least 2 months after completing the primary series.
  - J&J vaccine does not have eligibility criteria for the booster dose.

#### Resources:

Janssen COVID-19 Vaccine EUA

## FDA's Authorization of Heterologous (Mix-and-Match) Booster Dose

FDA amended the EUAs for COVID-19 vaccines to allow for the use of each of the available COVID-19 vaccines as a heterologous (or "mix and match") booster dose in eligible individuals following completion of primary vaccination with a different available COVID-19 vaccine. CDC's recommendations now allow for this type of mix and match dosing for booster shots. Heterologous dosing may be considered for the **booster dose** only.

#### Intervals of Heterologous (Mix-and-Match) Booster Dose

- Intervals should follow the interval recommended by the primary series.
- People who received a single dose Janssen primary series can receive a mRNA COVID-19 booster dose at least 2 months after completing primary series.
- If a Moderna vaccine booster is administered, the booster dose volume should be 50µg in 0.25ml (half-dose). Pfizer-BioNTech and Janssen booster doses are the same dose as primary vaccine. If an individual who is moderately to severely immunocompromised receives a primary dose of Janssen vaccine and receives a booster dose using Moderna, the 50µg dose should be used.

### **Vaccinate with Confidence**

Below are updated <u>resources</u> aimed at building confidence in COVID-19 vaccines.

- How to Build COVID-19 Vaccine Confidence in the Workplace
- Key Things to Know about COVID-19 Vaccines
- Frequently Asked Questions about Vaccination
- Vaccine Recipient Education
- Vaccine Communication Toolkit for Medical Centers, Clinics, Pharmacies, and Clinicians
- Ad Council: COVID-19 Collaborative Education Toolkit (Healthcare Provider Resources)
- HHS: COVID-19 Public Education Campaign Resources
- HHS: Talking Points for Health Care Leaders to Encourage Vaccine Confidence

#### **COVID-19 Vaccine and Clinical Information**

General information about COVID-19 vaccine products for clinicians and healthcare professionals can be found on the <a href="COVID-19 Vaccination webpage">COVID-19 Vaccination webpage</a>.

Clinical information including FAQs, Contraindications and Precautions as well as Administrative resources can be found for each vaccine on their own product webpage.

- Pfizer-BioNTech COVID-19 vaccine
- Moderna COVID-19 vaccine
- Janssen/J&J COVID-19 vaccine
- COVID-19 Vaccine Quick Reference Guide
- Interim Clinical Considerations Summary Document

#### V-Safe After Vaccination Health Checker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources.

- V-safe information sheet and poster: Posted on the Vaccine webpage and available in 5 languages: English, Spanish, Korean, Vietnamese, and Simplified Chinese
- V-safe after vaccination health checker website
- V-Safe Print Resources
- Vaccine Adverse Event Reporting System (VAERS)